

# Establishment of a measurement system to evaluate breast milk transfer of biological agents using dry filter paper: a multi-institutional study

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## Abstract

**Aims** Information on breastfeeding and the safety of biologics in infants is lacking due to difficulties in case collection. We evaluated a method for determining the concentration of biologics in breast milk using a dry filter method that can simplify the collection, storage, and transport of breast milk. **Methods** To generate dried filter paper (DFP) samples, approximately 30  $\mu$ L of breast milk was placed onto a Whatman 903 card and punched out. After extraction, the supernatant was measured using an enzyme-linked immunosorbent assay. Three concentrations of each drug were prepared in liquid breast milk (LBM) and DFP samples for stability testing, which confirmed that samples were stable up to 28 days after storage at 2–8 °C or -20 °C for LBM and at 25 $\pm$ 5 °C for DFP. LBM and DFP samples were provided by lactating mothers using biologics during lactation. Drug concentrations were compared. **Results** Breast milk was provided by 12 lactating mothers (tocilizumab, n=4; abatacept, n=2; etanercept, n=1; golimumab, n=1; sarilumab, n=1; and belimumab, n=3). The accuracy and precision of measurements for the six drugs were within acceptable limits. After 28 days, concentrations remained at more than 90% under all storage conditions. The quantitative values of the provided LBM and DFP samples were similar. The maximum relative infant dose ranged from 0.09% to 1.12%, which was an acceptable range. **Conclusion** A method for determining the concentration of biologics using DFP is expected to help improve pharmacotherapy for lactating women.

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